HEALTH AND SENIOR SERVICES

DIVISION OF HEALTH CARE SYSTEMS ANALYSIS

Certificate of Need:	Cardiac Diagnostic Facilities and Cardiac Surgery Centers
Proposed Amendments:	N.J.A.C. 8:33E
Authorized by:	Clifton R. Lacy, M.D. Commissioner, Department of Health and Senior Services (with the approval of the Health Care Administration Board)
Authority:	N.J.S.A. 26:2H-5 and 26:2H-8
Calendar Reference:	See Summary below for explanation of exception to calendar requirement.
Proposal Number:	PRN 2003-346
Submit comments by	October 17, 2003 to:

John A. Calabria, Director
Certificate of Need and
Acute Care Licensure Program
P.O. Box 360, Room 403
Trenton, New Jersey 08625

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) proposes amendments to N.J.A.C. 8:33E, Certificate of Need, Cardiac Diagnostic Facilities and Cardiac Surgery Centers, following consultation with the Commissioner's Cardiovascular Health Advisory Panel (CHAP), a review of pertinent research literature, clinical guidelines of the American College of Cardiology and the American Heart Association (ACC/AHA), an analysis of invasive cardiac diagnostic and therapeutic cardiac intervention performance data in New Jersey, a preliminary Statewide evaluation of physician and facility invasive diagnostic cardiac catheterization and therapeutic cardiac intervention performance levels, and recent clinical advances in cardiac care. In particular, the Department notes that clinical studies continue to reflect the efficacy of primary or emergency angioplasty for acute myocardial infarction (AMI) patients and the need to facilitate the availability of this emergency therapeutic cardiac intervention to all qualifying hospitals throughout New Jersey.

Previous rule amendments have established a process for evaluating potential providers of primary angioplasty in accordance with N.J.A.C. 8:33E-2.16. That process is further refined in this proposal, with the eligibility criteria amended to broaden the number of eligible potential

providers and permit potential providers that demonstrate unconditional compliance with all performance and quality measures and licensure requirements to initiate primary angioplasty services in a more timely manner.

The Department has continually recognized the importance of maintaining Statewide cardiac care policy that assures the provision of high quality cardiac services that are accessible and affordable to all New Jersey residents. For the past three decades, administrative rules for the full range of diagnostic and therapeutic cardiac services have been established and amended periodically by the Department. These amendments continue that effort by facilitating the allocation of cardiac service delivery based on sound clinical cardiac care and a thorough review of statewide cardiac performance data.

The Department is also well aware that there is continued interest in further development of new or expanded cardiac care services on the part of a significant number of acute care hospitals in the State. In an effort to be proactive and responsive to changes taking place in clinical cardiac care in an increasingly competitive health care environment, the Department continuously reviews cardiac facility and physician performance. Statewide data reporting requirements for both facilities and physicians have been greatly enhanced in recent years in order to provide

a quantitative and qualitative basis for the Department's regulatory activities. Most recently, the Department has begun the collection and analysis of Statewide full service cardiac catheterization services and therapeutic cardiac intervention services, thereby leading to a number of amendments in this proposal dealing with the standardization of the time frames to be used in future evaluations of physician and facility compliance with the minimum performance criteria contained in these rules.

The standards contained in this chapter establish minimum utilization, staffing and professional credentialing requirements that are designed to promote high quality invasive cardiac diagnostic services, therapeutic cardiac intervention services, and open heart surgery services by assuring appropriate staffing and volume levels to maintain professional skills and provide efficient and effective service. The proposed amendments reduce the minimum annual program volume requirement for both low-risk diagnostic catheterization laboratories and full service diagnostic catheterization laboratories. The Department has also added a quality-based cardiac surgery facility performance licensure standard that permits programs demonstrating lower than Statewide average mortality rates to continue in operation even if the annual facility volume requirement is not achieved.

This additional direct quality indicator is added in recognition of the fact that, while program volume is a well established surrogate measure of quality, there are exceptions that can be more appropriately evaluated using a direct patient outcome measure such as patient mortality. Since the Department incorporates in its Statewide cardiac surgery database outcome measures such as mortality at discharge and publishes a report periodically focusing on coronary artery bypass graft surgery, it is appropriate to incorporate into the rules a provision that permits a program with demonstrated lower than average mortality to continue in operation even if the volume standard is not achieved. Program volume requirements for other cardiac services and physician volume requirements are maintained without change.

A phase-in of interventional physician volume requirements is provided, however. The proposed amendments are expected to maintain program quality, assure the provision of safe, high quality care while increasing access to primary angioplasty. The impact on consumers is expected to be positive, since health care access will be broadened while quality is maintained through stringent licensure standards.

Briefly summarized, the Department's proposed amendments are as follows:

Consistent with recent Board of Medical Examiner rule amendments

(N.J.A.C. 13:35-4.1(c)) dealing with Physician Assistant (PA) and Registered Nurse First Assistant (RNFA) practice guidelines, PAs and RNFAs have been added to the list of eligible first assistants in an open heart surgery case (N.J.A.C. 8:33E-2.4(a)1ii).

The period of time that a full service cardiac provider must be licensed prior to being eligible to submit a certificate of need for primary angioplasty service delivery, in accordance with N.J.A.C. 8:33E-2.16(a), has been reduced from one year to six months.

Amended language at N.J.A.C. 8:33E-1.4(b)1 and 1.15(a)1 reduces the minimum facility utilization level (that is, from 500 to 400 cases), for potential new and existing full service cardiac catheterization providers. An additional amendment (N.J.A.C. 8:33E-1.15(a)) permits eligible low risk cardiac catheterization providers to submit certificate of need applications to upgrade their service to full service status on the first business day of each month, rather than the current limitation of January and July of each year. The applications will remain subject to the expedited rather than the full review process. The definitions of “full service adult diagnostic cardiac catheterization facility” at N.J.A.C. 8:33E-1.2 and 2.2 are also amended accordingly. Duplicate language at N.J.A.C. 8:33E-1.4(b)1 concerning the consequences of failure to maintain minimum facility volume is eliminated

and replaced with a reference to N.J.A.C. 8:33E-1.13, which contains similar language.

Additional language is added at N.J.A.C. 8:33E-1.4(b)3 to include specific reference to the provisions of N.J.A.C. 8:33E-1.13 in cases where full service diagnostic catheterization laboratories fail to achieve required minimum physician volumes.

Language is amended at N.J.A.C. 8:33E-1.4(c)1 that reduces the minimum annual facility volume for low risk diagnostic catheterization facilities from 350 to 200 patients per year. A new N.J.A.C. 8:33E-1.4(c)3 is added referencing the provisions of N.J.A.C. 8:33E-1.13(d) for low risk laboratories that fail to meet the minimum physician volume standards.

Additional language is added at N.J.A.C. 8:33E-2.3(d)4 indicating that annual physician volume for PTCA (that is, 75 cases annually as primary operator) is to be evaluated by the Department on a three-year phased-in basis, with a 50-case minimum annual volume required for the first two years and 75 cases required for the third year and annually thereafter. The evaluation of physician performance will continue to be calculated on a calendar year basis. Clarifying language is also added to indicate that physician volume may be accomplished at more than one laboratory in or out of State.

The definition of “normal coronary study,” as set forth at N.J.A.C. 8:33E-1.2 and 2.2 for diagnostic cardiac catheterization services, is amended to exclude the consideration of patients diagnosed with cardiomyopathy and congenital anomalies, previously considered as abnormal cases, from the calculation of a facility’s or physician’s percentage of normal studies.

N.J.A.C. 8:33E-1.3(a)3 is amended to add clarifying language that a low risk diagnostic catheterization facility does not have the availability of cardiac surgery services on-site. This is consistent with the language as set forth at N.J.A.C. 8:33E-1.3(a)2 , which contains the same language for full service cardiac catheterization facilities.

N.J.A.C. 8:33E-1.3(d) is amended to clarify that primary angioplasty services are to be provided to emergent patients that are experiencing an acute myocardial infarction, which, in effect, explains in clinical terms the emergent nature of the patient’s medical condition.

The language being deleted at N.J.A.C. 8:33E-1.4(c)1 is redundant, since the citation being added, N.J.A.C. 8:33E-1.13(d), contains the identical language. The Department’s intent is to reference the licensing evaluation process as set forth at N.J.A.C. 8:33E-1.13(d) rather than replicating this language for each individual cardiac diagnostic or therapeutic service throughout the chapter.

N.J.A.C. 8:33E-1.5(b)5 is amended to replace the word “constant” with “continuous” in characterizing the monitoring or recording that is to be performed by the cardiac catheterization technician.

N.J.A.C. 8:33E-1.5(b)6 is amended to update the responsibilities of the radiologic technician to include digital recording and additional language to indicate that skills now required may be superceded through widely accepted technological advances.

N.J.A.C. 8:33E-1.5(b)8 is amended to replace the word “bi-lingual” with “bi- or multi-lingual” in characterizing the availability of clinical personnel that may be necessary, dependent on an individual hospital’s patient population, to overcome language barriers and know and understand cultural differences among its patients.

New language is added at N.J.A.C. 8:33E-1.6(d)2 to indicate that the calculation of the normal study rate for low-risk diagnostic catheterization laboratories shall be made without use of a confidence interval.

Amended language has been added throughout the chapter clarifying the time frame for the evaluation of annual physician performance measures (that is, most recent calendar year available), to provide consistency of the time frames to be used to evaluate physician performance of cardiac catheterization (N.J.A.C. 8:33E-1.4(b)2ii and 2iii for full service; N.J.A.C. 8:33E-1.4(c)2ii and 2iii for low-risk), coronary

angioplasty or PTCA (N.J.A.C. 8:33E-2.3(d)4ii), cardiac surgery (N.J.A.C. 8:33E-2.4(a)1i(2)) and complex electrophysiology studies or EPS (N.J.A.C. 8:33E-2.3(e)4ii).

N.J.A.C. 8:33E-1.12, which provides for a one time call for applications to initiate low-risk diagnostic cardiac catheterization services, is repealed. The one time call referred to occurred in 2001, and, as a result, the provisions of this section no longer apply.

N.J.A.C. 8:33E-1.15(a) is amended to indicate that certificate of need applications for new full service cardiac catheterization services will be accepted on a monthly basis rather than semi-annually (that is, the semi-annual submission dates of January and July of each year are deleted from the text and replaced with the word each "month") in order to increase a potential provider's ability to upgrade its low risk cardiac catheterization service in a more timely manner and thereby improve access to full service cardiac catheterization.

N.J.A.C. 8:33E-2.1(f) is amended to clarify that cardiovascular surgical services include cardiac assist devices that require implantation. In addition, "balloon angioplasty" is deleted from the list of therapeutic catheterization procedures since balloon angioplasty is already included in the definition of percutaneous transluminal coronary angioplasty (PTCA) as set forth at N.J.A.C. 8:33E-2.2. The use of the term "balloon

angioplasty" is therefore redundant, since the all-inclusive term "PTCA" remains in the text.

Clarifying language is added at N.J.A.C. 8:33E-2.3(d) and (e) to emphasize that the enforcement process for failure to maintain minimum volume requirements applies equally to physician and program volume requirements.

N.J.A.C. 8:33E-2.3(d)3 is amended to clarify that primary angioplasty services are to be provided to emergent patients that are experiencing an acute myocardial infarction, which, in effect, explains in clinical terms the emergent nature of the patient's medical condition.

N.J.A.C. 8:33E-2.4(a)1ii is amended to indicate that a duly qualified physician assistant or duly qualified registered nurse first assistant may serve as an assistant to the physician in charge of the cardiac surgery operation. Furthermore, clarifying language is added to state that there shall be at least one surgeon and one duly qualified assistant in the operating room (rather than the previous requirement that two physicians were required to be present).

N.J.A.C. 8:33E-2.6, concerning the Commissioner's Cardiovascular Health Advisory Panel is repealed. The CHAP language at N.J.A.C. 8:33E-2.6 is proposed for deletion because

it is duplicative of language that appears at N.J.A.C. 8:33E-1.14. It is therefore redundant and can be deleted.

At N.J.A.C. 8:33E-1.1 and 2.2, the definition of "full service adult cardiac catheterization facility" (p. 19) is amended to clarify that the diagnostic services being provided are at a facility that does not have "cardiac" surgery services available on-site. (Clarification is needed that the Department's intent has been to indicate that cardiac surgery is not available at such facilities, since all licensed hospitals in New Jersey include general surgery as a mandatory service pursuant to N.J.A.C. 8:43G-2.12(a)15.)

N.J.A.C. 8:33E-2.14(a)1i is amended to state explicitly that a petitioner for a cardiac surgery call must demonstrate that it has at least 500 adult cardiac catheterization cases per year for the previous three years. This maintains the current volume requirement but must now be stated explicitly rather than by reference to the full service diagnostic laboratory minimum volume standard, which is now being proposed for reduction.

N.J.A.C. 8:33E-2.14(a)4 is amended to delete reference to publishing the timeframe for determination of completeness. In practice, variability in the number and complexity of applications makes it impossible for the Department to accurately estimate this timeframe.

N.J.A.C. 8:33E-1.3(d) is amended to correct the citation of the requirements for complex electrophysiology studies which can be found at N.J.A.C. 8:33E-2.3(e) rather than (d).

Additional rule citations are corrected throughout the chapter due to prior regulatory amendments or typographical errors. These corrections can be found at N.J.A.C. 8:33E-1.5(b)2i and (b)3, 1.7(a)1, 1.15(c), 2.3(b)3, 2.4(a)1iii, iv and v, 2.4(c)2, 2.4(e)1i, iii and iv, 2.4(f)1i, iii and iv, and 2.13(c). A typographical error has also been corrected in the definition of the term “satellite hospital” (N.J.A.C. 8:33E-2.2) which adds a hyphen to the term “non-inner city.”

Revised language at N.J.A.C. 8:33E-1.1(a) reflects the repeal in this proposal of N.J.A.C. 8:33E-1.12 that had been used to establish low risk cardiac catheterization programs.

Language regarding the prevalence of complications resulting from patients undergoing invasive cardiac techniques, as set forth at N.J.A.C. 8:33E-1.1(c), has been deleted. These complication rates were based on dated cardiac literature and no longer apply due to technological improvements in equipment and improved cardiac procedure techniques.

Revised language at N.J.A.C. 8:33E-2.3(a)2 and 2.13(a) adds a quality-based cardiac surgery facility performance licensure standard that permits programs demonstrating lower than Statewide average mortality

rates to continue in operation even if the annual facility volume requirement is not achieved.

Revised language at N.J.A.C. 8:33E-1.4(b)2 clarifies that the minimum annual physician volume for full service cardiac catheterization is 50 left heart catheterizations per year, which is identical to the requirement for physicians in low-risk cardiac catheterization laboratories as set forth at N.J.A.C. 8:33E-1.4(c)2.

N.J.A.C. 8:33E-2.14(a)4 is amended to delete reference to subparagraph (a)1i to clarify the Department's intent to require all certificate of need applicants for cardiac surgery, in the event of a successful petition, to address all of the criteria contained in subsection (a) in their certificate of need applications, regardless of whether the applicant did or did not file a petition under this section.

Grammatical errors were corrected where they existed and outdated clinical terminology was updated throughout the rule. None of these changes constitute a substantive change from the existing rules.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

N.J.S.A. 26:2H-1 et seq., as amended, recognizes as "public policy

of the State that hospitals and related health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost are of vital concern to the public health."

The 1990s were a decade of rapid change in New Jersey's healthcare delivery system. The Department recognizes the need to promote both quality and access in the delivery of services, particularly invasive diagnostic and therapeutic cardiac services, to all New Jersey residents, with particular emphasis on those population groups that have historically been under-represented in accessing these services (for example, minority and medically underserved populations). The cardiac literature continues to reflect a strong correlation between high volume and lower mortality and morbidity rates.

Additionally, the Department's extensive cardiac data have confirmed the relationship between volume and quality. Adjustments are being made to the required minimum volume standards for diagnostic catheterization facilities. Diagnostic procedures have proven to be very safe, and these changes can be made without compromising quality of care.

Access to primary or emergency angioplasty services is enhanced in this proposal by facilitating upgrade from a low risk to a full service cardiac catheterization provider, as well as expansion of full service providers into

primary angioplasty. The expedited review certificate of need process is retained, with potential primary angioplasty providers required to document a proven track-record of compliance with all licensing criteria and quality performance indicators. The process of upgrading low-risk cardiac catheterization services to full service status is also facilitated by permitting expedited review applications to be submitted monthly rather than current January and July submission dates.

Economic Impact

The costs to consumers are not expected to change as a result of adopting the proposed amendments. The costs to providers of implementing new cardiac services will be dependent on each individual hospital's need to renovate or construct the physical space required for the new cardiac service and each hospital's need to recruit additional staffing to meet minimum licensure requirements and thereby ensure a quality program. In some cases, particular hospitals with low risk laboratories seeking to expand service to all cardiac patients regardless of the degree of risk associated with each patient or full service laboratories seeking to initiate primary coronary angioplasty services, the additional capital costs will be minimal. Whatever the cost that may be incurred by each applicant, however, must be considered by each applicant and balanced with the increased patient census and reimbursement levels that

can be anticipated from the addition of the new or expanded service.

Federal Standards Statement

The proposed amendments do not impose standards on hospitals in New Jersey that exceed those contained in Federal law or regulation. Since there is currently no Federal regulation governing cardiac services, as described herein, a Federal standard analysis is not applicable to these proposed amendments.

Jobs Impact

Implementation of these proposed amendments provides clarification for requirements previously in effect and being administered; therefore, this rulemaking will have a limited impact on jobs. There are currently a limited number of cardiac catheterization providers and cardiac surgery centers that have been granted certificate of need approval under this chapter. This mix of providers is expected to change under the amended rules, with growth possible in the number of full service cardiac catheterization providers offset by a reduction in the number of low risk providers, and expansion of the number of primary angioplasty providers.

Agriculture Industry Impact

The proposed amendments will not have any impact on the agriculture industry.

Regulatory Flexibility Statement

The amendments proposed herein affect hospitals, which employ over 100 full-time employees. Thus, they are not defined as small businesses within the definition of that term, as set forth in N.J.S.A. 52:14B-15 et seq., and no regulatory flexibility analysis is necessary.

Smart Growth Impact

The proposed amendments will not have an impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets **[**thus**]**):

CHAPTER 33E

CERTIFICATE OF NEED: CARDIAC DIAGNOSTIC FACILITIES AND CARDIAC SURGERY CENTERS

SUBCHAPTER 1. CARDIAC DIAGNOSTIC FACILITIES

8:33E-1.1 Scope and purpose

(a) The purpose of this subchapter is to establish standards and general criteria for the planning of cardiac diagnostic facilities and for the

preparation of an application for a certificate of need for such a facility. The invasive cardiac diagnostic facility specializes in the detection and diagnosis of cardiac disorders. Unlike the cardiac surgery center in which both diagnostic and therapeutic services are co-located, the invasive cardiac diagnostic facility does not provide cardiac surgery or PTCA but rather on the basis of diagnostic studies refers patients, where appropriate, to facilities offering cardiac surgery and other advanced cardiac diagnostic and treatment modalities. To increase access to these services**,** **[**N.J.A.C. 8:33E-1.12 establishes**]** low risk cardiac catheterization programs **have been established** that are subject to facility performance standards contained at N.J.A.C. 8:33E-1.4(c) **[**, 1.12(c),**]** and 1.14 intended to ensure the continual delivery of safe**[**,**]** patient care, efficiently and effectively provided.

1. As of February 20, 1996, a new category of invasive cardiac diagnostic catheterization facility was established to treat only low risk adult patients **[**. Defined**]** **as** **defined** at N.J.A.C. 8:33E-1.2**[**, these facilities may apply for a certificate of need in response to a call under criteria as set forth at N.J.A.C. 8:33E-1.12**]**.

(b) In the invasive cardiac diagnostic facility, the primary diagnostic services are provided by cardiac catheterization, coronary angiographic and non-invasive laboratories. The cardiac catheterization and coronary

angiographic laboratories are devoted to achieving optimal quality physiological and angiographic studies. Non-invasive cardiac diagnostic services are commonly available at all acute care hospitals and may include, at a minimum, **[**ECG instruments**]** **electrocardiography**, exercise stress testing, **[**Doppler technology/**]**echocardiography **[**equipment and Holter type**]** monitoring**,** and nuclear cardiology **[**facilities**]**.

(c) The American College of Cardiology/American Heart Association Task Force on Cardiac **[**catheterization**]** **Catheterization** supports the position that the safety and efficacy of laboratory performance requires a caseload of adequate size to maintain the skills and efficiency of the staff. **[**Death or serious nonfatal complications of myocardial infarction and/or cerebral embolus occurs in 1.5 percent of the population examined by invasive techniques. Such problems occur 10 times more often in institutions performing fewer than 100 examinations per year than in those performing 400 examinations annually.**]** In the interest of patient care, then, it is important to encourage optimal utilization of diagnostic resources. It is also essential that in view of the invasive nature of the cardiac catheterization procedure and the extent of possible complications associated with these procedures, cardiac surgery services must be accessible promptly, either in-house or by immediate transfer, in the event of an emergency or complication. Finally, catheterization must

be performed in a laboratory that is physically part of, and is a permanent structure within, a health care facility offering inpatient support services.

(d) (No change.)

8:33E-1.2 Definitions

For the purposes of this subchapter, the following definitions shall apply:

...

"Cardiac surgery center" refers to a facility capable of providing invasive diagnostic catheterization, and all treatment modalities including open and closed heart surgical procedures. This includes: coronary artery bypass graft (CABG) surgery, PTCA**,** and complex EPS studies.

...

"Full service adult diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services to adult patients without **cardiac** surgery backup. These facilities have laboratories which must meet the requirement of procedures performed on at least **[**500**]** **400** patients annually.

...

"Left-heart catheterization" refers to the measurement of left heart hemodynamics and definition of the left heart anatomy/function by catheter-delivered radiopaque contrast media.

…

“Normal coronary study” means a clinical finding subsequent to the performance of a cardiac catheterization procedure indicating less than 50 percent stenosis in all of the following arteries: left main, proximal left anterior descending (LAD), **[**other LAD,**]** right coronary artery (**[**RAC**]RCA**) or **left** circumflex **(LCX)**. **[**Any**] A finding of any** stenosis of greater than or equal to 50 percent is considered an abnormal cardiac catheterization study. A finding of valvular disease **[**, cardiomyopathy or congenital disorders are**] is** to be considered as **an** abnormal finding**[**s**]** in a study. **A case in which there is a finding of cardiomyopathy or congenital cardiac disorder shall be excluded from the normal coronary study calculation.**

"Open heart surgery" refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct **[**anomalic**] anomalous** conditions (for example, coronary artery bypass surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

...

8:33E-1.3 General criteria for invasive cardiac diagnostic facilities

(a) For the purpose of certificate of need application and licensure, invasive cardiac diagnostic facilities shall be categorized as follows:

1.-2. (No change.)

3. Low-risk diagnostic cardiac catheterization facility **(without cardiac surgery)**; and

4. (No change.)

(b)-(c) (No change.)

(d) Complex electrophysiology studies (EPS) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site. Facilities providing complex EPS shall also be required to meet all applicable standards and criteria at N.J.A.C. 8:33E-2.3**[**(d)**](e)**. Elective PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent **during acute myocardial infarction**) PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E-2.16.

8:33E-1.4 Utilization criteria for invasive cardiac diagnostic facilities

(a) (No change.)

(b) Except as specifically set forth with respect to low risk cardiac catheterization facility, at (c) below, all facilities licensed to provide full service invasive cardiac diagnostic services shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per full service cardiac laboratory is **[**500**]** **400** per year. New full service providers (those previously operating as low risk cardiac catheterization laboratories) must provide documentation of full compliance with the minimum utilization level during their second year of operation or their most recent four quarters of operation, whichever is later and fully documented by the Department using audited data. Existing full service invasive cardiac diagnostic providers (with or without cardiac surgery on site) must achieve minimum utilization levels each year. Compliance with minimum annual facility volume requirements will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those new and existing full service laboratories unable to achieve the minimum level as set forth in this

paragraph will be **subject to the provisions of N.J.A.C. 8:33E-1.13.** **[**required to submit to the following:

i. An external review from an independent external organization approved by the Department to assess the overall performance of the facility and its staff;

ii. A detailed plan of correction must be submitted to the Department within 30 days of notification of its failure to maintain compliance with annual minimum facility volume standard in N.J.A.C. 8:33E-1.4(b)1 above and physician volume standard in N.J.A.C. 8:33E-1.4(b)2 below. Where applicable, plans of correction must be submitted indicating the licensure renewal criteria that have not been achieved, the corrective actions that are to be put in place or the systemic changes that will be employed to ensure future compliance, a timetable for compliance, and the methods used to monitor future actions to ensure eventual compliance. This plan of correction may include a formal request for waivers to licensure requirements as set forth at N.J.A.C. 8:43G-2.8. The plan of correction will not be considered final until it has been approved by the Department;

iii. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables will result in a revocation of the facility's license unless an appeal is filed with the Commissioner

within 60 days after receiving the department's notice of revocation. The department may issue a notice of revocation up to 12 months after the facility's licensure anniversary date following the earliest compliance date within the plan of correction in which the facility was deficient. If the facility requests a hearing, it will be held in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules N.J.A.C. 1:1. At the Commissioner's discretion, the hearing will be conducted by the Commissioner or transferred to the Office of Administrative Law. In exercising discretion, the Commissioner may consider the following:

(1) The scope and severity of the threat;

(2) The frequency of the occurrence;

(3) The presence or absence of attempts at remedial action by the facility;

(4) The presence or absence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat; and

(5) Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients.**]**

2. Each physician must perform **left heart catheterizations** **[**procedures**]** on a minimum of 50 patients **[**a**]** **per** year **[**with a minimum of

100 patients over a two year period**]**. (This minimum caseload may be accomplished at more than one laboratory in or out of State). For the Director of the laboratory, the standard is left-heart catheterizations on 150 patients per year, at least 100 of which must be performed at the full service laboratory of which the physician is Director.

i. (No change.)

ii. Compliance with the physician's minimum annual patient volume for cardiologists with laboratory privileges shall be based on the most recent calendar year's performance data available prior to the hospital's licensure anniversary date.

iii. Compliance with the Director's minimum annual patient volume, which includes the total number of catheterizations performed Statewide and the number of cases performed in the Director's laboratory, shall be based on the most recent four quarters of data available to the Department prior to the low risk laboratory's licensure anniversary date.

3. Those new and existing full-service laboratories unable to achieve the minimum volume levels set forth in this subsection shall be required to submit to the process that has been established at N.J.A.C. 8:33E-1.13.

(c) All facilities licensed to provide invasive cardiac diagnostic services pursuant to low risk catheterization facility standards described in this subchapter shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per year is **[**350**]** **200**. Those laboratories unable to achieve this minimum level by the end of the second year of operation as set forth at N.J.A.C. 8:33E-1.13, will be required to submit to the **process that has been established at N.J.A.C. 8:33E-1.13(d).** **[**following:

i. An external review from an independent external organization approved by the Department to assess the overall performance of the facility and its staff;

ii. A detailed plan of correction must be submitted to the Department within 30 days of notification of its failure to maintain compliance with annual minimum facility volume standard in N.J.A.C. 8:33E-1.4(c)1 above and physician volume standard in N.J.A.C. 8:33E-1.4(c)2 below. Where applicable, plans of correction must be submitted indicating what licensure renewal criteria are deficient, what corrective actions are to be put in place or what systemic changes will be employed to ensure future compliance, a timetable for compliance, and the methods

used to monitor future actions to ensure eventual compliance. This plan of correction may include a formal request for waivers to licensure requirements as set forth at N.J.A.C. 8:43G-2.8. The plan of correction will not be considered final until it has been approved by the Department;

iii. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables will result in a revocation of the facility's license unless an appeal is filed with the Commissioner within 60 days after receiving the department's notice of revocation. The Department may issue a notice of revocation up to 12 months after the facility's licensure anniversary date following the earliest compliance date within the plan of correction in which the facility was deficient. If the facility requests a hearing, it will be held in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules N.J.A.C. 1:1. At the Commissioner's discretion, the hearing will be conducted by the Commissioner or transferred to the Office of Administrative Law. In exercising discretion, the Commissioner may consider the following:

(1) The scope and severity of the threat;

(2) The frequency of the occurrence;

(3) The presence or absence of attempts at remedial action by the facility;

(4) The presence or absence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat; and

(5) Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients.**]**

2. Physicians practicing in hospitals operating a low risk catheterization facility shall meet minimum volume criteria. For the Director of the laboratory, the standard is left-heart catheterizations on 150 patients per year, at least 100 of which must be performed at the low**-**risk laboratory of which the physician is Director. For other physicians with privileges in the low risk laboratory, the standard is left-heart catheterizations on 50 patients per year. (This minimum caseload may be accomplished at more than one laboratory in or out of State.)

i. (No change.)

ii. Compliance with the physician's minimum annual patient volume for cardiologists with laboratory privileges shall be based on the most recent calendar year's performance data available prior to the hospital's licensure anniversary date.

iii. Compliance with the Director's minimum annual patient volume, which includes the total number of catheterizations performed Statewide and the number of cases performed in the

Director's laboratory, shall be based on the most recent four quarters of audited data available to the Department prior to the low-risk laboratory's licensure anniversary date.

3. Those low-risk laboratories unable to achieve the minimum volume levels as set forth in this subsection shall be required to submit to the process that has been established at N.J.A.C. 8:33E-1.13(d).

8:33E-1.5 Facility personnel

(a) (No change.)

(b) While the following functions shall be performed within each facility, more than one function may be executed by a single individual if that individual has been appropriately cross-trained to perform the required functions:

1. The laboratory director (physician in charge) shall be the chief diagnostician within the unit, and shall be certified by the Cardiovascular **[**Sub-Specialty**]** **Subspecialty** Board of the American Board of Internal Medicine or by the **[**Sub-Specialty**]** **Subspecialty** Board of Pediatric Cardiology of the American Board of Pediatrics. In addition to Board certification, the director shall have broad experience and training in invasive cardiac diagnostic procedures, including, but not limited to, a

minimum of 12 months in a cardiac catheterization training program and the performance of 200 cardiac catheterization procedures with 100 of these procedures performed as the primary operator.

2. Associate physicians may be assigned to the laboratory and shall meet the identical training requirements for laboratory director contained in (b)1 above. In addition, all catheterizing physicians shall adhere to the minimum physician volume standards established for each laboratory in accordance with N.J.A.C. 8:33E-1.4(b)2 and (c)2, whichever is applicable.

i. Exceptions to these minimum training and certification requirements for incumbent Directors and associate physicians requirements may be granted by the Commissioner upon application by an institution providing documentation as to the physician's qualifications, in accordance with the requirements of this chapter, N.J.A.C. 8:43G-7.15(b), **[**7.40, 7.28,**]** **7.25 and 7.44;** and N.J.A.C. 13:35.

3. The registered nurse shall assist with administration of medications and the preparation and observation of the patient. The nurse shall have **[**intensive**]** cardiac **intensive** care unit **[**(ICCU)**]** **(CCU)** experience, shall meet the licensing requirements specified at N.J.A.C. 8:43G-7.15**[**(d)**](e)**, and shall have knowledge of cardiovascular

medications, experience with catheterization and, for pediatric cardiac surgery centers, pediatric experience.

4. The cardiac catheterization technician shall handle blood samples and assist in the performance **of** tests. The technician shall help in the maintenance of equipment and supplies and should be trained to aid in patient observation and acute cardiac care.

5. The cardiac catheterization technician shall be responsible for **[**constant**]** **continuous** monitoring and recording of all physiologic data including the electrocardiogram.

6. The radiologic technician shall be skilled in conventional radiography and shall have special training and skills in angiographic techniques. This technician shall be competent in magnification radiography, subtraction photography, cine recording, television presentations and the use of videotape**, and digital recording, except that skill in techniques that have been superceded through widely accepted technological advances shall no longer be required. This technician shall [** and**]** be responsible for the care and maintenance of all radiologic equipment.

7. (No change.)

8. Hospitals providing invasive cardiac diagnostic services should, to the extent possible, have bi**- or multi-**lingual clinical personnel available

who can overcome language barriers and know and understand cultural differences among patients.

(c) (No change.)

8:33E-1.6 Quality Improvement

(a)-(c) (No change.)

(d) All facilities applying to provide or providing a low risk cardiac catheterization facility or a full service adult diagnostic cardiac catheterization facility shall also provide written documentation that the proposed services shall adhere to the following quality of care outcome measures:

1. (No change.)

2. A physician-specific and overall low risk laboratory percentage of normal studies that does not exceed 25 percent of total annual cardiac catheterization cases **calculated without application of a confidence interval**;

3.-5. (No change.)

(e) (No change.)

8:33E-1.7 Community outreach, access and prevention

(a) Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter shall develop and maintain appropriate mechanisms to assure access to services and to promote cardiac health among the underserved population in its service area which shall include, but not necessarily be limited to, the following components:

1. All hospitals, including those participating as a low risk catheterization facility, shall document their community prevention services for all populations, specifically targeting minorities, elderly and under-12 population groups, in accordance with license renewal standards at N.J.A.C. 8:33E-1.13 **[**and 1.14**]**. Examples of community prevention programs are those primary and secondary prevention initiatives which include: diet and drug therapy for hypercholesterolemia in patients at high risk or with established coronary artery disease: smoking cessation programs with objective outcome measures; exercise rehabilitation programs for patients with established coronary artery disease; and public education programs.

2.-3. (No change.)

8:33E-1.9 Data reporting

(a) Every facility licensed to provide invasive cardiac diagnostic services in accordance with this subchapter shall maintain and provide

statistical patient level data on the operation of the program and report those data to the Department of Health and Senior Services on a quarterly basis and in a standardized format determined by the Department. These cumulative patient level data will be submitted to the Department of Health and Senior Services on a quarterly basis, within 30 days after the close of the quarter. Copies of the full text of the required quarterly reporting forms may be obtained upon written request to The New Jersey State Department of Health and Senior Services, Division of Health Care Systems Analysis, Research and Development Program, P.O. Box 360, Trenton, New Jersey 08625.

1. In addition to the reporting requirements of paragraph (a) above, statistical data submitted by all facilities licensed to provide low risk invasive cardiac diagnostic services pursuant to the low-risk catheterization facility described in this subchapter must, prior to submission to the Department, be audited and verified by an independent auditing body approved by the Department. Each low risk catheterization program will be responsible for the entire cost of its own audits and shall provide the Department with any and all documentation substantiating the findings of the auditor for compliance with utilization and quality standards at N.J.A.C. 8:33E-1.4 and 1.6. This independent auditing requirement shall apply only to low risk catheterization facilities.

8:33E-1.12 [Requirements for submission of certificate of need applications to provide low risk invasive cardiac diagnostic services as a low risk catheterization facility] (Reserved)

[(a) Applications to initiate low risk invasive cardiac diagnostic services will only be accepted in response to a one-time call for such services to be issued at the discretion of the Commissioner. All such applications will be processed on an expedited review basis pursuant to N.J.A.C. 8:33-5.

(b) All applications to initiate low risk invasive cardiac diagnostic services shall include full written documentation of the projected implementation and operational costs of the proposed program. This documentation shall include direct and indirect costs, that is, construction, equipment, supplies, personnel, maintenance, overhead costs, as well as projected costs of remodeling or renovation necessary to accommodate the program. Projection of anticipated revenues shall be supplied for at least the first three years. Failure to include such documentation will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33-4.5.

(c) All applications to initiate low risk invasive cardiac diagnostic services pursuant to the low risk catheterization facility described in this subchapter shall also include documentation of compliance with the applicable standards and criteria of this subchapter specifically those set forth at N.J.A.C. 8:33E-1.3 through 1.10. Failure to include such documentation at the time of filing will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33-4.5.

(d) Except where specifically exempted or superseded, all applications to initiate low risk invasive cardiac diagnostic services shall be in addition to and not in limitation of any other applicable certificate of need provisions of this subchapter; N.J.S.A. 26:24-1 et seq.; N.J.A.C. 8:33; and N.J.A.C. 8:43G.

(e) All applicants, through a resolution of its Board of Directors, shall acknowledge and accept the standards and criteria set forth herein as conditions of approval and agree to be bound by all provisions of this chapter, and particularly with respect to the licensure requirements in N.J.A.C. 8:33E-1.13. Failure to include such documentation at the time of filing will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33-4.5.**]**

8:33E-1.15 Requirements for submission of certificate of need applications to provide full service invasive cardiac diagnostic services.

(a) Applications to provide new full service invasive cardiac diagnostic services pursuant to the requirements in this subchapter will be accepted on a **[**semi-annual**]** **monthly** basis, with all such applications to be submitted on the first business day of **[**January and July of**]** each **[**year**]** **month**. Such applications will be processed on an expedited review basis pursuant to N.J.A.C. 8:33-5.1(b)2. Eligibility for the submission of such applications will be limited to the following:

1. Licensed providers of low-risk cardiac catheterization services that have demonstrated full unconditional compliance with State licensure requirements that includes, but is not limited to, compliance with the minimum annual facility volume requirement for full service cardiac catheterization (that is, **[**500**]** **400** cases) as set forth at N.J.A.C. 8:33E-1.4(b)1 throughout their second year of operation or their most recent four quarters of operation, whichever is later and fully documented by the Department using audited data. Failure to include such documentation will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33-4.5.

(b) (No change.)

(c) Except where specifically exempted or superseded, all applications to convert low risk invasive cardiac diagnostic services pursuant to the criteria described in this subchapter shall be in addition to and not in limitation of any other applicable certificate of need provisions of this subchapter; N.J.S.A. **[**26:24-1 et seq.**]** **26:2H-1 et seq.**; N.J.A.C. 8:33; and N.J.A.C. 8:43G.

SUBCHAPTER 2. REGIONAL CARDIAC SURGERY CENTERS

8:33E-2.1 Scope and purpose

(a)-(c) (No change)

(d) At a minimum, the non-invasive laboratory shall include the **[**following facilities**]** **capability to perform the following services**:

1. **[**ECG instruments**]****Electrocardiography**;
2. Exercise Stress **[**testing**]** **Testing**;
3. Echocardiography **[**equipment**]**;
4. **[**Holter-type monitoring**]****Ambulatory Electrocardiographic Monitoring**; and
5. Nuclear **[**cardiology**]****Cardiology**.

(e) (No change.)

(f) The cardiovascular surgical services include open heart, closed heart and coronary artery surgery**[**, as well as**];** surgery of the great vessels**[**,**]; and implantation of** cardiac assist devices, such as the intra-aortic balloon pump. Therapeutic catheterization procedures include PTCA **[**or balloon angioplasty**]**. The requirements contained in this subchapter for facilities, personnel and equipment for open heart surgery shall be the minimum requirements for all cardiovascular surgical and interventional cardiology procedures.

8:33E-2.2 Definitions

For the purposes of this subchapter, the following definitions shall apply:

...

"Full service adult diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive, cardiac diagnostic (cardiac catheterization) services to adult patients without surgery **cardiac** backup. These facilities have laboratories which must meet the higher requirement of procedures performed on at least **[**500**] 400** patients annually.

...

"Left-heart catheterization" refers to the measurement of left heart hemodynamics and definition of left heart anatomy/function by catheter**-** delivered radiopaque contrast media.

…

“Normal coronary study” means a clinical finding subsequent to the performance of a cardiac catheterization procedure indicating less than 50 percent stenosis in all of the following arteries: left main, **[**proximal**]** left anterior descending (LAD), **[**other LAD,**]** right coronary artery (**[**RAC**]RCA**) or circumflex**(LCX)**. **[**Any**] A finding of any** stenosis of greater than or equal to 50 percent is considered an abnormal cardiac catheterization study. A finding of valvular disease **[**, cardiomyopathy or congenital disorders are**] is** to be considered as **an** abnormal finding**[**s**]** in a study. **A case in which there is a finding of cardiomyopathy or congenital cardiac disorder shall be excluded from the normal study calculation.**

…

"Open heart surgery" refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct **[**anomalic**] anomalous** conditions (for example, coronary artery bypass

surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

...

"Satellite hospital" means a non-inner city licensed acute care hospital which is a member of a hospital system containing an inner city teaching hospital and which is permitted to provide invasive therapeutic cardiac services through implementation of an inner city cardiac satellite demonstration project, in accordance with this chapter.

...

8:33E-2.3 Utilization of cardiac surgical centers

(a) The following shall apply to adult cardiovascular surgical units:

1. (No change.)

2. All existing regional adult cardiac surgical centers shall continue to perform at least 350 open heart surgical procedures per year to **[**insure**]** **ensure** the competency of the surgical services team and to provide for efficient and economical operation. Compliance with this annual facility volume requirement will be calculated on the basis of the last four quarters of data submitted to and reviewed by the Department prior to the facility's licensure anniversary date. **Facilities that perform fewer than 350 open heart surgical procedures per year shall alternatively achieve a risk-**

adjusted mortality rate (mortality at discharge) for isolated coronary artery bypass graft (CABG) surgery for the most recent four quarters that is lower than the statewide observed mortality rate (mortality at discharge) for isolated CABG surgery (the alternative method).

i. Data for calculating a facility's risk-adjusted isolated CABG mortality rate shall be derived from the Department's open heart data base.

ii. The Statewide observed isolated CABG mortality rate shall be the Statewide rate for the most recent calendar year reported in the Department's most recent published report on cardiac surgery performance.

iii. Calculation of a facility's risk-adjusted mortality rate shall be based on the risk-adjustment model used to create the Department's most recent published report on cardiac surgery performance. However, there shall be no use of a confidence interval in determining how a facility's risk-adjusted mortality rate compares to the Statewide observed mortality rate.

iv. The facility risk-adjusted and Statewide observed mortality rates shall be expressed as a percentage calculated to two decimal places.

v. A facility that demonstrates compliance through the alternative method shall be licensed unconditionally for the licensure period. However, a sample of patient medical records designated by the Department shall be examined in a timely fashion by a Department-approved auditor at the facility's expense to confirm the accuracy of the information relevant to the risk-adjustment calculation submitted by the facility to the Department's open heart data base. Audit results shall be submitted directly by the auditor to the Department. If audit adjustments result in a revised facility risk-adjusted mortality rate that is higher than the Statewide observed mortality rate, then the facility shall be licensed conditionally and the provisions of N.J.A.C. 8:33E-2.13(a) shall apply.

3. (No change.)

(b) The following shall apply to pediatric cardiac diagnostic and surgical services:

1.-2. (No change.)

3. The minimum acceptable number of pediatric cardiac catheterization patients per invasive pediatric cardiac diagnostic laboratory is 150 per year. New pediatric surgical centers shall achieve this minimum level of utilization in their invasive pediatric cardiac diagnostic laboratory within three years from the initiation of the service. As cited at

N.J.A.C. 8:33E-**[**1.2(e)**]** **1.3(e)**, pediatric patients requiring invasive cardiac diagnostic procedures shall undergo these procedures only in centers with invasive pediatric cardiac diagnostic and pediatric cardiac surgery programs.

4. (No change.)

(c) (No change.)

(d) The following shall apply to adult cardiac surgery centers providing or seeking to provide percutaneous transluminal coronary angioplasty (PTCA) services:

1. An applicant for a certificate of need as a regional adult cardiac surgery center that also seeks to provide PTCA services in its invasive cardiac diagnostic laboratory must provide written documentation that the center will perform a minimum of 200 PTCA procedures per year by the third year of operation. A regional adult cardiac surgery center with the inability to achieve minimum utilization levels **for either the program or individual physicians** during the third year of operation or thereafter will be required to submit to the process that has been established at (d)2 below.

2. A regional adult cardiac surgery center shall continue to perform a minimum of 200 PTCA procedures annually in order to assure acceptable institutional quality. Existing cardiac surgery centers providing

PTCA shall comply with this utilization standard on an annual basis. Compliance with minimum annual facility volume requirements for PTCA will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those existing or new cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter **for either the program or individual physicians** will be required to submit to the following:

i.-iii. (No change.)

3. Elective PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent **during acute myocardial infarction**) PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E-2.16.

4. Each PTCA facility shall establish a minimum number of PTCA procedures for each physician with PTCA laboratory privileges. Each physician performing PTCA procedures as the primary operator shall perform a minimum of 75 PTCA cases a year**[**, 150 PTCA cases over a two year period (excluding the physician's first year of clinical practice following completion of training)**]**. **(This minimum caseload may be accomplished at more than one laboratory in or out of State.) The**

physician's minimum annual patient volume is to be achieved at the end of a three year phase-in period, requiring 50 PTCA cases as primary operator during the first (CY 2003) and second year (CY 2004), and 75 PTCA cases by the end of the third year (CY 2005) and annually thereafter. **[**Compliance with annual physician volume standards will be calculated on a calendar year basis.**]**

i. Exceptions for cardiologists to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform PTCA; physician not a member of the staff for an entire year; new program in operation less than one year require only timely written notification to the Department. Any other extraordinary circumstances will require the submission by the hospital of a written waiver request in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G-2.8. **[**Compliance with physician volume standards will be calculated on a calendar year basis.**]**

ii. Compliance with the physician's minimum annual patient volume for cardiologists with laboratory privileges shall be based on the most recent calendar year's performance data available prior to the hospital's licensure anniversary date.

(e) The following shall apply to adult cardiac surgery centers providing or seeking to provide complex electrophysiology studies.(EPS):

1. An applicant for a certificate of need as a regional adult cardiac surgery center that also seeks to provide complex electrophysiology studies or an existing, cardiac surgery center seeking to initiate complex electrophysiology services must provide written documentation that the center will perform a minimum of 100 electrophysiology studies per year, with at least 50 of these studies representing initial studies of patients. These new complex electrophysiology services must achieve this minimum utilization level within three years of operation. A regional adult cardiac surgery center with the inability to achieve minimum utilization levels **for either the program or individual physicians** during the third year of operation or thereafter will be required to submit to the identical process that has been established at (e)2 below.

2. A regional cardiac surgery center shall continue to perform a minimum of 100 complex electrophysiology studies annually in order to assure acceptable institutional quality. Existing cardiac surgery centers providing complex electrophysiology studies shall comply with this utilization standard on an annual basis. Compliance with minimum annual facility volume requirements for complex EPS will be calculated on the basis of the last four quarters of operation prior to the facility's licensure

anniversary date. Those existing or new cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter **for either the program or individual physicians** will be required to submit to the following:

i.-iii. (No change.)

3. (No change.)

4. Each complex electrophysiology service shall establish a minimum number of complex electrophysiology studies for each physician with electrophysiology laboratory privileges. A minimum of 50 complex electrophysiology cases a year, with at least 25 as initial studies, shall be maintained to preserve a consistent level of proficiency. **[**Compliance with annual physician volume standards will be calculated on a calendar year basis.**]**

i. Exceptions for cardiologists to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform complex EPS; physician not a member of the staff for an entire year; new program in operation less than one year require only timely written notification to the Department. Any other extraordinary circumstances will require the submission of a written waiver request by the hospital in accordance with the hospital licensing waiver

provisions as set forth at N.J.A.C. 8:43G-2.8. **[**Compliance with physician volume standards will be calculated on a calendar year basis.**]**

ii. Compliance with the physician's minimum annual patient volume for cardiologists with laboratory privileges shall be based on the most recent calendar year's performance data available prior to the hospital's licensure anniversary date.

8:33E-2.4 Cardiac surgery center personnel

(a) The following shall apply to cardiovascular surgical units:

1. Cardiac surgery is most successful when performed by a smoothly functioning team. The basic team of the regional cardiac surgical center shall consist of the following permanently assigned staff:

i. One physician in charge of the operation (that is, primary surgeon), board-certified by the American Board of Thoracic and Cardiovascular Surgery as a cardiovascular surgeon who directs the team or the surgical unit. A minimum of 100 cases per year shall be performed by each cardiac surgeon as the primary surgeon on any case. This volume shall be achieved at each licensed site in New Jersey at which the physician practices as primary surgeon on any case**[**;**]**.

(1) (No change.)

(2) Exceptions for surgeons to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform surgery; physician not a member of the staff for an entire year; new program in operation less than one year require only timely written notification to the Department. Any other extraordinary circumstances will require the submission of a written waiver request by the hospital in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G-2.8. **[**Compliance with physician volume standards will be calculated on a calendar year basis;**]** **Compliance with the physician's minimum annual patient volume for physicians with cardiac surgery privileges shall be based on the most recent calendar year's performance data available prior to the hospital's licensure anniversary date;**

ii. One assistant to the physician in charge of the operation who will be a board qualified surgeon. A cardiothoracic surgery resident or fellow **or a duly qualified physician assistant or duly qualified registered nurse first assistant, in accordance with N.J.A.C. 13:35-4.1(c),** may serve as an assistant. There shall be **[**two**]** **at least one** surgeon**[**s**]** **and one duly qualified assistant** in the operating room;

iii. An anesthesiologist, meeting the licensing requirements contained at N.J.A.C. 8:43G-7.5**[**(c)**]** **(d)** 1 and 2 shall be responsible for the anesthetic management of cardiac surgery patients. This anesthesiologist may be assisted by additional personnel as specified at N.J.A.C. 8:43G-7.5 **[**(d)**]** **(e)**;

iv. There shall be at least one registered nurse and an assistant meeting licensing requirements at N.J.A.C. 8:43G-7.5 **[**(h)**]** **(i)** in each operating room;

v. In accordance with N.J.A.C. 8:43G-7.5 **[**(i)**]** **(j)**, a perfusionist who is certified by the American Board of Cardiovascular Perfusion or meets the experience requirements shall be available to operate the perfusion pump for each cardiac surgical procedure. A second perfusionist meeting the same requirements shall be available in the surgical suite to assist. In emergency cases**,** a second perfusionist may be off-site and readily summoned if needed;

vi. A cardiovascular nurse specialist (one for every 100 open heart procedures) and a physician's assistant may be employed to supplement the cardiovascular surgical team**[**.**]**; and

vii. (No change.)

2. (No change.)

(b) The intensive care cardiac recovery room (or Surgical **[**Critical**]** **Intensive** Care Unit (**[**SCCU**]****SICU**)) is the area where cardiac patients are held for postoperative care. At a minimum, patient coverage in this area shall be on a one specially trained cardiac nurse to one patient basis for the first 24 hours after surgery or in accordance with the diagnosis. During this period of intensive care the operating surgeon and team or qualified alternate shall be on call. Clinical appropriateness may permit the patient to be transferred sooner than 24 hours to a step-down unit where the above 1:1 nursing to patient ratio does not apply. After a full 24 hours following the operative day, and in accordance with patient diagnosis, nursing coverage may be reduced to a maximum of three patients to two nurses during the second and third days following the operative day as long as ventilatory and other life support systems have been discontinued.

1.-2. (No change.)

(c) The following shall apply to cardiac diagnostic facilities located in a cardiac surgery center.

1. (No change.)

2. Exceptions to these minimum training and certification requirements for incumbent directors and associate physicians may be granted by the Commissioner and upon application by an institution

providing proper documentation as to the physician's qualifications, in accordance with the requirements of this chapter, N.J.A.C. 8:43G-7.15(b), **[**7.40 and 7.28,**]** **7.25 and 7.44;** and N.J.A.C. 13:35.

(d) (No change.)

(e) The following shall apply to invasive cardiac diagnostic facilities located in cardiac surgery centers that seek to perform percutaneous transluminal coronary angioplasty (PTCA):

1. Each invasive diagnostic facility must be staffed, at a minimum, by the following personnel during a PTCA procedure:

i. The physician directing the procedure shall be a board certified cardiologist with well-recognized excellence in the management of routine cardiac catheterization and who has participated in a minimum of 100 PTCA procedures (with at least 50 as primary operator) and meets the licensing qualifications specified at N.J.A.C. 8:43G-**[**7.23(a)**]** **7.29(a)**;

ii. (No change.)

iii. A registered nurse meeting the licensing requirements specified at N.J.A.C. 8-43G-**[**7.24(a)2**]** **7.30(a)**2 shall be available to assist with PTCA procedures; and

iv. One assistant meeting the licensing requirements specified at N.J.A.C. 8:43G-**[**7.24(a)3**]** **7.30(a)3** shall be available to assist with PTCA procedures.

(f) The following shall apply to invasive cardiac diagnostic services located in cardiac surgery centers that seek to perform complex electrophysiology studies (EPS):

1. Each invasive cardiac diagnostic service shall be staffed, at a minimum, by the following personnel during a complex electrophysiology study.

i. The physician directing the procedure must be a board-certified cardiologist with well-recognized excellence in the management of routine cardiac catheterization who has obtained at least one additional year of specialized training in complex EPS and cardiac arrhythmias including participation in 100 complex EPS procedures, and meets the licensing qualifications specified at N.J.A.C. 8:43G-**[**7.26(a)**]** **7.32(a)**.

ii. (No change.)

iii. A registered nurse meeting the licensing requirements specified at N.J.A.C. 8:43G-**[**7.27(a)2**]** **7.33(a)**2 shall be present during the procedure.

iv. One assistant meeting the licensing requirements specified at. N.J.A.C 8:43G-**[**7.27(a)3**]** **7.33(a)3** shall be present during the procedure.

8:33E-2.5 Use of inpatient facilities

(a) In a center performing 350 open heart surgical cases annually, the following inpatient facilities shall be required:

1. An intermediate intensive care/cardiac care unit will be available for post-operative care. It shall include four beds for patients having an average length of stay of three to four additional days following discharge from the **[**SCCU**]** **SICU** or surgical recovery room. These beds may be located in a cardiovascular step-down unit with telemetry monitoring but reduced nursing coverage consistent with licensing requirements at N.J.A.C. 8:43G-9.20 and in accordance with patient diagnosis. Suitably equipped beds will be available for the rest of the patient's stay. At a minimum the intensive care/cardiac care unit will have the following capabilities**:**

i. **[**Facilities for hemodynamic**]** **Hemodynamic** ECG monitoring:

ii. Temporary pacemaker insertion:

[iii. C.P.R. equipment;

iv. Arrhythmia detection equipment:**]**

[v.**]** **iii.** Resuscitative equipment **and supplies, including defibrillator and cardiac emergency medications** ; and

[vi**]** **iv**. (No change in text.)

3:33E-2.6 [Commissioner's cardiovascular health

advisory panel (CHAP)] (Reserved)

[(a) A cardiovascular health advisory panel has been established, under the authority of the Commissioner of Health and Senior Services to provide the Commissioner with expert clinical and/or technical advice required for the development of sound cardiovascular health policy. The committee panel shall also:

1. Assist in the development of Statewide cardiovascular health promotion and disease prevention activities;

2. Review cardiac service technological developments and provide advice on the degree to which these developments have been integrated into the accepted standards of practice;

3. Provide advice on implications of changes in technology and/or patterns of practice for State standards and criteria for cardiac services;

4. Advise on Statewide issues regarding cardiac care: and

5. Advise on the development and implementation of Statewide cardiac research and data activities.**]**

8:33E-2.10 Data to be maintained and reported

(a) Every cardiac facility licensed to provide therapeutic interventional cardiac-procedures that include, but are not limited to, cardiac surgery and PTCA or coronary angioplasty services in accordance

with this subchapter shall maintain and provide data on patient characteristics and outcomes, services to medically underserved populations, community outreach, and individual program components as determined by the Department. All hospitals shall report these data to the Department of Health and Senior Services on a quarterly basis and in a standardized format determined by the Department. If necessary to determine whether a facility is in compliance with this chapter, the Department shall require that the data submitted shall be audited at the hospital's expense by an independent third party approved by the Department.

1. The criteria for auditor approval are as follows:

i.-iii. (No change.)

iv. Auditing firms shall identify and contract with at least two board certified cardiologists then in practice to review data from which medical diagnoses are made. The two cardiologists shall not be on staff at the audited facility. They shall be certified by the Cardiovascular **[**Sub-Specialty**]** **Subspecialty** Board of the American Board of Internal Medicine. They shall have broad experience and training in invasive cardiac therapeutic procedures, including, but not limited to, a minimum of 12 months in an invasive therapeutic cardiac services program and the

performance of at least 200 invasive cardiac therapeutic procedures, with 100 of those procedures performed as the head cardiologist.

v.-vi. (No change.)

2. – 3. (No change.)

8:33E-2.13 Compliance

(a) Existing pediatric and adult cardiac surgery centers shall continue to meet the minimum criteria and standards contained in this subchapter on an annual basis. Compliance with minimum annual facility volume**/quality** requirements will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those existing cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter will be required to submit to the following:

1.-3. (No change)

(b) (No change.)

(c) Notwithstanding the duration of unimplemented certificates of need criteria as set forth at N.J.A.C. 8:33-3.10, all certificate of need applications for new pediatric and adult cardiac surgery services approved after the effective date of these rules shall have two years from the date of certificate of need approval to initiate such services by obtaining licensure

approval. In accordance with N.J.A.C. 8:33-3.10(a)**[**4**]** **3**, failure to implement the project within two years will result in the automatic termination of the certificate of need, unless the Commissioner determines that the failure of the applicant to complete the project within the timeframe was the result of extraordinary unforeseeable circumstances beyond the control of the applicant. In accordance with N.J.A.C. 8:33-3.10(a), extension of time requests shall be filed within 60 days prior to the current certificate of need expiration date and shall include detailed documentation of the following:

1.-3. (No change.)

8:33E-2.14 Petition for and submission of certificate of need applications

(a) All certificate of need applicants seeking to initiate cardiac surgical services shall be subject to the requirements of this subchapter, as applicable, and the following:

1. The Department shall only process certificate of need applications for the initiation of cardiac surgical services in accordance with procedures set forth below and in N.J.A.C. 8:33. Certificate of need applications shall only be accepted for processing from general hospitals after a hospital has petitioned the Department and established the

potential need for new cardiac surgery services by demonstrating that it meets the following minimum standards, which indicate a potential unmet need and that the petitioner is qualified to meet the unmet need:

i. The petitioner is an existing provider of full service invasive cardiac diagnostic services that has complied with all applicable requirements at N.J.A.C. 8:43G-7 and this chpater and has for the previous three years **[**met or exceeded the minimum acceptable number of **]** **had at least 500** adult cardiac catheterization cases **[**required for a full service cardiac laboratory in accordance with N.J.A.C. 8:33E-1.4(b)1**]** **per year,** as demonstrated by the most current data maintained by the Department;

ii.-v. (No change.)

2.-3. (No change.)

4. Within 60 days of the Commissioner's determination that a petitioner has met the minimum standards necessary to issue a regional call for submission of certificate of need applications for a new cardiac surgery program, the Commissioner shall publish a call. The call shall: invite cardiac surgery applications from any general hospital, including petitioner, located in the petitioner's county or a contiguous county that meets the criteria set forth in (a)1 **[**i**]** above. It will also invite existing New Jersey cardiac surgery centers located in the petitioner's county or a contiguous county ("affected facilities") to file a

written submission with the Department in response to any submitted certificate of need applications that have been deemed complete. The published call shall set forth timeframes for the submission of applications, **[**the determination of completeness of the applications, **]**the opportunity for affected facilities to obtain copies of the applications, and the written submissions by affected facilities responding to the applications.

i.-ii. (No change.)

8:33E-2.15 Competitive review criteria

(a) (No change.)

(b) During certificate of need review, consideration for approval shall be limited to the applicant(s) that meets the following requirements and does so to a greater extent than the competing applicants, has documented compliance with the following competitive review criteria and has documented compliance with all other applicable criteria in this subchapter and N.J.S.A. 26:2H-8. Unless otherwise specified in the certificate of need call issued by the Commissioner, a maximum of one new cardiac surgery program shall be considered for approval in any certificate of need call under these competitive review criteria.

1. The applicant is able to provide quantifiable documentation of its historic commitment to access to cardiac services, including preventive

and primary cardiac services as well as invasive cardiac diagnostic services, for minority and medically underserved populations;

i. The applicant shall provide documentation**,** which shows the proportion of minority and medically underserved residents residing in the proposed service area, which shall be no larger than the county in which the applicant is located as well as contiguous counties;

ii. (No change.)

2.-8. (No change.)

8:33E-2.16 Submission of certificate of need applications for the provision of PTCA in emergent situations with off-site cardiac surgery back-up

(a) The Department's goal in considering applications for provision of PTCA without the availability of on-site cardiac surgery in emergent situations is to promote wider access to appropriate emergency PTCA services while assuring quality of care to patients with acute myocardial infarction. Certificate of need applications shall be accepted on the first business day of each month and shall follow the expedited review process.

1. Any general hospital having a full service adult diagnostic cardiac catheterization program **that has been licensed for at least six**

months as a full service adult diagnostic cardiac catheterization program prior to the application submission date may apply provided it has documented, to the satisfaction of the Department, licensure and full compliance with all cardiac catheterization program and facility utilization requirements as set forth in this chapter and N.J.A.C. 8:43G for the most recent four quarters of operation fully documented by the Department.

(b)-(e) (No change)